REMARKS

The continued examination of the current application is respectfully requested pursuant to 37 C.F.R. § 1.114 (**RCE**). Pursuant to this continued examination, it is respectively requested that the above amendments be considered in view of the following remarks, and that all claims pending in this application be allowed. Claims 1-6 are pending in the instant application.

Claims 1 and 6 have been amended to further clarity the subject matter Applicants regard as the invention. Support for the amendments to the claims is located at least in the claims as filed and throughout the specification, especially on page 1, line 10 to page 2, line 15, and page 3, lines 14-23. Applicants reserve the right to file a Continuation or Divisional Application directed to any subject matter canceled by way of this Amendment.

I. REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 1-6 have been rejected under 35 U.S.C. § 112, second paragraph as indefinite because of the recitation of the term "propagating the viruses of each type or species on cells which are permissive for the viruses but which do not induce any viral interference". Applicants respectfully submit that the skilled artisan would know what is meant by "interference" and "permissive" in the context of the present invention. In support of this argument and to further clarify the present invention, Applicants submit

are defined as "Cells in which replication of a particular virus can take place."

"Interference" is defined as the "prevention of the replication of one virus by another". Specifically, the present invention is primarily concerned with heterologous interference. As discussed in the provided definition of "interference", heterologous interference occurs between two different species of virus. Thus, Applicants submit that the skilled artisan would know what is meant by "interference".

Further, the present invention addresses the problem of assaying viruses in a composition containing different serotypes of viruses. Previously in the art, it was difficult, if not impossible, to neutralize some viruses without interfering with the virus one wishes to assay. The present invention provides methods of enable a complex viral composition to be titered without modifying the viruses contained therein. *See* present specification, pages 1-2. The outstanding Office Action states that "one cannot determine what is intended by 'interference' since a permissive cell by definition is impacted or interfered with by the infecting virus". In light of the above reference and remarks, Applicants submit that upon reading the specification, the skilled artisan would know that in the context of the present invention, 'interference' refers to when one species of virus interferes with replication of another species of virus. Interference is a problem in the art, as discussed in the specification of the present invention, and is one which the present invention has overcome, for purposed of titering viral serotypes.

In light of the above remarks, withdrawal of the rejection is respectfully requested.

VI. REJECTIONS UNDER 35 U.S.C. § 102(b)

For proving anticipation, "anticipation requires the presence in a single prior art disclosure of all elements of a claimed invention as arranged in the claims." Jamesbury Corp. v. Litton Industrial Products, Inc. 225 U.S.P.Q. 253, 256 (Fed. Cir. 1985). The cited references do not describe or suggest all of the elements of the rejected claims, as discussed in greater detail below.

The present invention addresses the well known problem of how to titrate the quantity of each type of virus from a complex composition containing many different serotypes of virus. For example, a composition may contain different subtypes of Dengue virus, different subtypes of polio virus or different subtypes of rotavirus. Previously, it was difficult, if not impossible, to titrate one viral subtype in the composition without changing the quantity of viruses of the other subtypes also present.

To address this problem, the present invention claims a method of determining the virus quantity of each species in a composition which contains different species and/or types of live virus. These methods do not induce viral interference and thus do not affect the quantities of the other subtypes of virus present in the sample.

Ibanez-Bernal et al. Claims 1-4 stand rejected under 35 U.S.C. § 102(b) as purportedly anticipated by Ibanez-Bernal et al. Ibanez-Bernal et al. (Medline Abstract/

monoclonal antibodies.

Independent claim 1 has been amended herein to recite using a "specific monoclonal antibody wherein the quantity of each type or species of virus is determined". Thus, the claims now recite a method step directed to quantification of the different serotypes used in the present invention.

As the Ibanez-Bernal et al. reference does not anticipate the claimed invention, as amended herein, Applicants respectfully request the withdrawal of the rejection.

Shaw et al. Claim 5 stands rejected under 35 U.S.C. § 102(b) as purportedly anticipated by Shaw et al. Shaw et al. (Medline Abstract/ *Gastroenterology* (1987) 93:941-950) is cited for purportedly disclosing serotype-specific monoclonal antibodies directed at VP7 in a competitive solid-phase immunoassay to measure epitope specific immune responses to serotypes 1, 2 and 3.

Claim 1 has been amended to recite monoclonal antibodies which are serotype specific. Not all of the antibodies of Shaw et al. are serotype specific. Because the Shaw et al. reference does not anticipate the claimed invention, as amended herein, Applicants respectfully request the withdrawal of the rejection.

Osterhaus et al. Claim 6 stands rejected under 35 U.S.C. § 102(b) as purportedly anticipated by Osterhaus et al. Osterhaus et al. (Medline Abstract/ *Developments in*

polio virus types 1, 2 and 3.

Claim 6 of the present invention is directed to a composition which contains different subspecies of rotavirus. The outstanding Office Action notes that Applicants previous argument that the cited reference does not disclose the propagation of the viruses present in the sample on cells which are permissive for the viruses and do not induce any viral interference is not relevant to claim 6. However, Applicants note that claim 6 is dependent on claim 1, which requires that the propagation of the viruses present in the sample on cells which are permissive for the viruses and do not induce any viral interference. In the interest of clarity, claim 6 has been amended herein to recite "serotypes" of virus, rather than "types" of virus. Applicants further note that claim 1 has been amended to recite "wherein the quantity of each type or species of virus is determined; and wherein the monoclonal antibodies are serotype specific", further distinguishing the claims from the cited references.

As discussed above, the present invention addresses the problem of how to titrate the quantity of each type of virus from a complex composition containing many different serotypes of virus.

Claim 6, as dependent on claim 1, is directed to a method for determining the virus quantity of each of the virus types or virus species in a composition which contains different species or types of live virus, comprising the following steps: propagating the viruses of each type or species on cells which are permissive for the viruses and which do

and wherein the monoclonal antibodies are serotype specific.

In contrast, Osterhaus et al. do not disclose as the elements of the claimed invention, as required by 35 U.S.C. § 102. Osterhaus et al. disclose that the monoclonal antibodies may be useful for vaccine control purposes. As disclosed in the preamble of the present specification, the neutralization of monoclonal antibodies was well known in the art. However, the inventive step of the instant invention is the ability to determine the virus quantity of each of the virus types in a composition which contains different species or types of live virus, without affecting the quantity of the other species of virus present. Osterhaus et al. fail to disclose this element of the claimed invention. Thus, Osterhaus et al. do not disclose these required elements of the claimed invention.

Also, Applicants note that the Osterhaus et al. reference relates to polio, yet is cited against current claim 6, which is directed to rotavirus. Shaw et al, which relates to rotavirus, is cited against claim 5, which is directed to polio virus.

As the Osterhaus et al. reference does not anticipate the claimed invention, Applicants respectfully request the withdrawal of the rejection.

CONCLUSION

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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ATTACHMENT TO REPLY AND AMENDMENT UNDER 37 C.F.R. § 1.114 (RCE)
MARKED-UP CLAIMS 1 AND 6

1. (Three Times Amended) A method for determining the virus quantity of each of the virus types or virus species in a composition which contains different species or types of live virus, comprising the following steps:

- propagating the viruses of each type or species on cells which are permissive for the viruses and which do not induce any viral interference, and
- assaying each type or species of virus using a specific monoclonal antibody wherein the quantity of each type or species of virus is determined;
and wherein the monoclonal antibodies are serotype specific.

6. (Three Times Amended) The method according to claim 1, wherein the composition comprising different species or serotypes [types] of live virus is a composition which comprises different types of rotavirus.